

Application No.: 10/616,769
Amendment dated: October 25, 2007

Docket No.: 66535DIV (46590)

REMARKS

Claims 1, 9, 11, 15, 29, 34, and 36-38 are pending in this application. Claims 2-8, 10, 12-14, 16-28, 30-33, 35, 39-42, 44 and 46-58 have been canceled. Claim 1 and 29 have been amended. Support for the amended claim and added claim can be found throughout the specification and drawings of the application as filed. No new matter has been added by amending claims 1 and 29.

1. Claims 1, 9, 11, 15, 29, 34, 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating senile dementia of Alzheimer's disease with the compounds herein wherein A is those defined in claim 9, and Y is those defined in claim 11, does not reasonably provide enablement for treating senile dementia of Alzheimer disease with any other compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Examiner states, "The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. The court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and 8) the breadth of the claims.

The claims are broadly cover method of treating senile dementia of Alzheimer's disease with compounds defined by the general

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formula in claim 1, which essentially encompasses unlimited number of compounds with various structurally distinct features. The specification discloses particular compound 1 and 5 have shown excellent NGF and BDNF production/secretion promoting activity (experimental example 1). The specification provide no working examples, or any rationale that compounds other than those closely related to compounds 1 and 5, i.e. the compounds wherein R1 is amidazolyl group which may optionally be substituted, A is a phenoxy group substituted with an alkyl groups which may optionally be substituted, B is a phenyl group which may optionally be substituted, and Y is divalent hydrocarbon group, would be similarly effective as compounds 1 and 5, so that be useful for treating senile dementia of Alzheimer's disease. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The court in *In re Fisher*, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statute. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology of Alzheimer's disease. Further, various structural distinct compounds herein deemed to present unpredictability as to their physiological properties. For examples, Compounds with A as C1-4 alkoxy groups are reasonably expected to be different from those with A as phenoxy group. The difference of the sizes, shapes and electronic distribution of the A would certainly affect the physical and chemical properties of the compounds and thereby affects the physiological property. Further, the flexible divalent carbon group as Y certainly has distinct affect compared with heterocyclic group. In the instant case, the art and the evidence presented in the instant application fails to establish support for treatment of senile dementia of Alzheimer's disease with compounds other than those closely related to compounds 1 and 5, i.e. the compounds wherein R1 is amidazolyl group which may optionally be substituted, A is a phenoxy group substituted with an alkyl groups which may optionally be substituted, B is a phenyl group which may optionally be substituted, and Y is divalent hydrocarbon group, as instantly claimed. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

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Applicants respectfully disagree. Applicants wish to clarify that "a C₁₋₄ alkoxy" of "A represents a phenoxy group substituted with an alkyl group which may optionally be substituted or a C₁₋₄ alkoxy" in claim 1 is a substituent on the "phenoxy group", Applicants refer to the definition of A to read as follows (support in the specification: page 27, line 2).

"A represents (i) a phenoxy group substituted with an alkyl group which may optionally be substituted or (ii) a phenoxy group substituted with a C₁₋₄ alkoxy"

Furthermore, Applicants have amended the definition of Y in claims 1 and 29 to "a divalent hydrocarbon group".

In the Office Action, the Examiner holds that the compounds closely related to compounds 1 and 5 would be similarly effective as compounds 1 and 5, so that be useful for treating senile dementia of Alzheimer's disease.

The compound (1) described in Experimental Example is 4-(4-chlorophenyl)-5-[3-(2-methoxyphenoxy)propyl]-2-(2-methyl-1-imidazolyl)oxazole (specification page 29, lines 23-24), which is a compound wherein A is a 2-methoxyphenoxy. Accordingly, the specification provides enablement for treating senile dementia of Alzheimer's disease with the compound of the present invention wherein A is a phenoxy group substituted with a C₁₋₄ alkoxy.

Applicants submit that all claims are allowable as amended and respectfully request early favorable action by the Examiner. Applicant's representative would like to discuss this case with the Examiner to learn if any outstanding issues remain after consideration of this Amendment. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record. Although it is not believed

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that any further fee is needed to consider this submission, the Office is hereby authorized to charge our deposit account 04-1105 should such fee be deemed necessary.

Early consideration and allowance of the above-captioned application is respectfully requested.

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Respectfully submitted,



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